

## BUREAU OF HEALTH

Chapter 265: MAINE DRUG TESTING LABORATORY RULES

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Summary: The Department of Human Services has prescribed these rules and regulations for programs and laboratories testing employees and applicants for substances of abuse. The rules are intended to assure that employees and applicants receive reliable and accurate testing, and that privacy rights are protected.

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## A. Definitions

As used in this chapter, unless otherwise indicated, the following terms have the following meanings.

1. Applicant. "Applicant" means any person seeking employment from an employer. The term includes any person using an employment agency's services.
2. Employee. "Employee" means a person who is permitted, required or directed by any employer to engage in any employment for consideration of direct gain or profit.
3. Employer. "Employer" means any person,, partnership, corporation, association or other legal entity, public or private, that employs one or more employees. The term also includes an employment agency.
4. Negative test result. "Negative test result" means a test result that indicates that:
  - (a). A substance of abuse is not present in the tested sample; or
  - (b). A substance of abuse is present in the tested sample in a concentration below the cutoff level.
5. Positive test result. "Positive test result" means a test result that indicates the presence of a substance of abuse in the tested sample above the cutoff level of the test.
  - (a). "Confirmed positive result" means a confirmation test result that indicates the presence of a substance of abuse above the cutoff level.
6. Substance abuse test. "Substance abuse test" means any test procedure designed to take and analyze body fluids or materials from the body for the purpose of detecting the presence of substances of abuse. The term does not include tests designed to determine blood alcohol concentration levels from a sample of an individual's breath.
  - (a). "Screening test" means an initial substance abuse test performed through the use of immunoassay technology, or a test technology of similar or greater accuracy and reliability approved by the department of Human Services as

specified in these rules, section D(8), and which is used as a preliminary step in detecting the presence of substances of abuse.

(b). "Confirmation test" means a 2nd substance abuse test performed through the use of gas chromatography mass spectrometry that is used to verify the presence of a substance of abuse indicated by an initial positive screening test result.

7. Substance of abuse. "Substance of abuse" means any scheduled drug, alcohol or other drug, or any of their metabolites.

(a). "Alcohol" has the same meaning as found in Title 28-A, MRSA, section 2, subsection 2: The substance known as ethyl alcohol, hydrated oxide of ethyl, or spirit of wine which is commonly produced by the fermentation or distillation of grain, starch, molasses, sugar, potatoes or other substances, and includes all dilutions and mixtures of these substances.

(b). "Drug" has the same meaning as found in Title 32, section 13702, subsection 9:

(1). Articles recognized as drugs in the official United States Pharmacopoeia and National Formulary, other drug compendiums or any supplement to any of them;

(2). Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals;

(3). Articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and

(4). Articles intended for use as a component of any articles specified in paragraphs I to 3." (c). "Scheduled drug" has the same meaning as found in Title 17-A, section 1101, subsection 11: any drug named or described in section 1102, schedule W, X, Y, or Z.

## B. Collection and storage of Samples

For all testing allowed under these rules, the specimen to be collected shall be the employee's or applicant's urine, except that, as provided by Title 26, MRSA, section 683, subsection 5, employees may request that a blood sample be collected for testing for alcohol and/or marijuana metabolites, provided that a laboratory is available to the employer or applicant which is in compliance with all other sections of these rules concerning laboratories, and which offers testing for alcohol or marijuana metabolites in compliance with such rules. If such a blood sample is requested, the employer may not test any other sample for alcohol or marijuana metabolites.

1. The collection of any sample for use in a substance abuse test must be conducted in a medical facility and supervised by a physician licensed under Title 32, MRSA, chapter 36 or 48, or a

nurse licensed under Title 32, MRSA, chapter 31. A medical facility includes a first aid station located at the work site.

2. An employer may not require an employee or applicant to remove any clothing for the purpose of collection a urine sample, except that:
  - (a). An employer may require that an employee or applicant leave any personal belongings other than clothing and any unnecessary coat, jacket or similar outer garments outside the collection area; or
  - (b). If it is the standard practice of an off-site medical facility to require the removal of clothing when collecting a urine sample for any purpose, the physician or nurse supervising the collection of the sample in that facility may require the employee or applicant to remove their clothing.
3. No employee or applicant may be required to provide a urine sample while being observed, directly or indirectly, by another individual.
4. Urine samples shall be collected in new, clean containers manufactured for the purpose of urine collection. If the employer's policy calls for specimen assessment, the person in charge of collection, may, in the presence of the test subject, measure the temperature of the specimen within 3 minutes of voiding, the pH of the specimen, and evaluate the color and odor of the specimen. The container shall be sealed and labeled immediately after collection and specimen assessment in a manner which will prevent or reveal tampering with the specimen. Seals shall cover the cap and extend over the sides of the container. The specimen container shall be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling shall occur under the observation of the employee or applicant being tested.
5. Blood specimens, where allowed, shall be collected in new vacuum-activated blood collection tubes, with such preservatives as may be specified by the testing laboratory, and shall be sealed with tamperproof seals, covering the cap and extending over the sides of the container. Blood samples shall be taken by a licensed physician, registered physician's assistant, registered nurse, or a person certified by the Department of Human Services to draw blood under Code of Maine Rules, 10-144A, chapter 268. Each specimen container shall be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling shall occur under the observation of the employee or applicant being tested.
6. Immediately upon collection of each sample, a chain of custody record shall be established for that sample, indicating the identity of each person having control over the sample, and the times and dates of all transfers or other actions pertaining to the sample. If the volume of testing warrants, chain of custody records may be maintained in a log book or other custody form for

multiple specimens, provided the identity of each specimen can be documented.

7. Samples shall be transported or shipped promptly to the testing laboratory in a secure fashion, so as to prevent tampering. If shipment or transport is not feasible, the specimens shall be refrigerated within one hour, at less than 6° C for no more than three days, or frozen at -20° C or less, for no more than two weeks before shipment.
8. At the request of the employee or applicant, a portion of the sample, collected, sealed, and labeled according to the above procedures, shall be segregated for that person's own testing. This sample shall be stored and chain of custody shall be maintained as provided above. If the employer does not have the capability to store segregated samples for the necessary time period, such storage may be arranged with the licensed testing laboratory performing the employer's analyses, provided that all chain of custody and security requirements are otherwise met. Within 5 days after sample collection, the employee or applicant shall notify the employer of the testing laboratory selected for that person's own testing. The laboratory so selected shall comply with all the requirements of these rules relating to testing laboratories. The Employer, or the employer's laboratory, shall promptly send the segregated portion of the specimen to the selected laboratory, subject to the same chain of custody and security requirements as observed for the employer's specimen.

C. Substances for which testing is permitted.

Employers may require testing of employees and applicants for the following substances and groups of substances, as allowed for in a Department of Labor approved policy. Except for assessing specimen integrity, no other testing is permitted. Employers shall specify to the testing laboratory which substances are to be tested for in each specimen or group of specimens.

1. Substances or groups of substances shall include amphetamine/methamphetamine, barbiturates, cannabinoids, benzodiazepines, cocaine and/or metabolites, phencyclidine, opiates, methaqualone, methadone, and alcohol.
2. Minimum reportable levels (cutoff levels) for the initial screening test will be established by laboratories and employers at levels (in urine, unless otherwise specified) no lower than the following

amphetamine/methamphetamine	1000	ng/ml
barbiturates	300	ng/ml
cannabinoids in urine	50	ng/ml
cannabinoids in blood	10	ng/ml
benzodiazepines	300	ng/ml
cocaine and/or metabolites	300	ng/ml
phencyclidine	25	ng/ml
opiates	2000	ng/ml
methaqualone	300	ng/ml
methadone	300	ng/ml
alcohol in blood or urine	0.02	g/100ml

3. Threshold detection levels for confirmatory tests will be established by laboratories at levels (in urine, unless otherwise specified) no lower than the following

6-acetyl morphine (only if morphine>2000)	10	ng/ml
amphetamine/methamphetamine	500	ng/ml
barbiturates	300	ng/ml
cannabinoids in urine	15	ng/ml
cannabinoids in blood.	10	ng/ml
benzodiazepines	200	ng/ml
cocaine and/or metabolites	150	ng/ml
phencyclidine	25	ng/ml
opiates (morphine, codeine)	2000	ng/ml
methaqualone	300	ng/ml
methadone	300	ng/ml
alcohol in blood or urine	0.02	g/100ml

D. Testing Laboratories.

Laboratories testing for substances of abuse shall comply with all of the following requirements, except as noted.

1. Licensure.

(a). Laboratories testing for substances of abuse under these rules must be licensed by the Department of Human Services for such testing. Application for licensure shall be made by the Laboratory owner on forms prescribed by the Department, and shall be accompanied by a non-refundable fee of ~~\$500.00~~ following Chapter 257:SCHEDULE OF CHARGES OF THE DIAGNOSTIC LABORATORY OF THE DEPARTMENT OF HUMAN SERVICES as provided by 22 MRSA, section 562.

(b). The term of the license shall be one year from the date of issue. Application for renewal must be received by the Department of Human Services at least one month before the expiration date of the current license. Application for renewal shall be accompanied by a non-refundable fee of ~~\$300.00~~, following Chapter 257:SCHEDULE OF CHARGES OF THE DIAGNOSTIC LABORATORY OF THE DEPARTMENT OF HUMAN SERVICES as provided by 22 MRSA section 562.

(c). Laboratories shall document compliance with all of the provisions of these rules, and shall be subject to inspection by representatives of the Department of Human Services. Initial inspection of a laboratory applying for licensure shall be conducted by the Department of Human Services within 60 days of the Department's receipt of the application and confirmation of necessary documentation. If the laboratory is found to be in compliance with these rules, licensure shall be effective the date of the inspection. If the laboratory is not in compliance, licensure shall be effective on submission and completion of a satisfactory plan of correction, or such other action as shall be needed to bring the facility into compliance. Repeat inspection may be required by the Department.

(d). Subsequent inspections shall be conducted at least 2 times per year, and at 3 month intervals for the first 6 months of licensure. If the Laboratory is found to be not in

compliance, it must submit an acceptable plan of correction with 10 days. In the event of continuing non-compliance, the Department may seek revocation of the laboratory's license pursuant to 5 MRSA, chapter 375, subchapter V. In the case of laboratories located outside the state of Maine, the laboratory shall be liable for all travel, per diem, lodging, and other costs of the inspection. Laboratories shall be subject to inspection at all times during operating hours.

- (e). Laboratories shall notify the Department of any changes in personnel, procedures, or other factors material to the quality of testing, within 10 days of occurrence.
  - (f). Laboratories may be licensed upon application, without inspection, if the laboratory is approved by the National Institute on Drug Abuse program for accreditation of drug testing laboratories, or licensed by the New York State Department of Health program for licensing of drug testing laboratories.
- 2. Laboratories shall be in full compliance with the provisions of the Maine Medical Laboratory Act, Title 22, MRSA, sections 2011 - 2040.
- 3. No employer may perform any substance abuse test administered to any of that employer's employees. As provided by law, employers may perform screening tests on their own applicants, provided the employer's testing facility complies with the requirements of section D.
- 4. The Laboratory shall have a Director who shall assume professional, organizational, educational, and administrative responsibility for the laboratory's drug testing facility
  - (a). The Director shall have documented scientific qualifications in analytical forensic toxicology. At a minimum, these qualifications are:
    - (1). An earned doctoral degree in the physical, chemical or biological sciences from an accredited institution, with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology, or an equivalent educational background, and
    - (2). Certification in at least one laboratory specialty by the American Board of Pathology, the American Osteopathic Board of Pathology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Forensic Toxicology, and
    - (3). Appropriate experience in analytical forensic toxicology including experience with analysis of biological material for drugs of abuse and appropriate training and/or experience in forensic applications, of analytical toxicology, e.g. publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors to qualify the individual as an expert witness in forensic toxicology.

- (b). The Director must participate in the daily management and operation of the laboratory. The director is responsible for ensuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory, and that a complete, signed and dated procedure manual and adequate quality assurance programs are in place. If the Director is not a full time employee, at least one certifying officer shall have equivalent qualifications.
5. The laboratory shall designate one or more certifying officer(s), who may be the director. The certifying officer(s) shall be (a) full time employees. The certifying officer(s) shall be qualified, by both formal training and laboratory experience, in performance and supervision of drug testing. The certifying officer must review the standards, blanks, and quality control data together with the screening and confirmation test results. Upon assurance that all results are acceptable, the certifying officer certifies the test result or results before reporting.
6. Supervisors must be on the premises at all times testing is being performed. Supervisors must possess at least a baccalaureate degree in chemistry, biochemistry, or other physical or biological science, and have received at least 20 semester hours of training in chemistry, and have experience comparable to that required by the Maine Medical Laboratory rules for Supervisors, as found in 10-144A, CMR, Chapter 256. The supervisor must have training in the theory and practice of the procedures used, and understanding of quality control concepts. The supervisor shall have 2 or more years of experience in the principles and practices of toxicology. Periodic verification of skills must be documented.
7. Other technical and non-technical staff must possess the necessary training and skills for the task assigned. In-service continuing education programs to meet the needs of all laboratory personnel are desirable. Personnel files must include: resume of training and experience, certification or license if any, references, job descriptions, records of performance evaluation and advancement, and incident reports. Tests for color blindness must be administered and documented where necessary for the assurance of proper work.
8. The laboratory must have clear written procedures describing the chain of custody of all samples, the security requirements for all sections of the laboratory, including the security of record keeping, and for all laboratory testing procedures and quality assurance procedures. Screening, and confirmatory methods of testing and assessing specimen integrity shall be as provided by law, except that alternative screening methodologies may be approved by the Department upon written application by the laboratory. The Department shall respond to such application within 30 days.
9. The laboratory must demonstrate satisfactory performance in the proficiency testing program of the National Institute on Drug Abuse, the College of American Pathologists, or the American Association for Clinical Chemistry, for each substance of abuse for which testing services are offered.

- (a). Documentation of enrollment in an approved proficiency testing program and copies of results must be provided to the Health Laboratory by the proficiency testing service, or by submission to the Department of Human Services of certified copies of such documents by the laboratory.
  - (b). Satisfactory performance is defined as follows:
    - (1). For each survey, achieving an 80% accuracy rate with no false positives.
    - (2). Perform satisfactorily for two of every three consecutive surveys.
    - (3). For consecutive surveys, achieve an accuracy rate on each substance of  $66 \frac{2}{3} \%$  with no false positives.
    - (4). Prior to initial licensure, achieve an 80% accuracy rate with no false positives for 2 consecutive surveys.
  - (c). All unsatisfactory results must be investigated to determine the cause of the unsatisfactory result. In those instances where a false positive result was reported, a retrospective investigation of client specimen records must take place to determine if similar errors had occurred. This investigation must be documented and a copy of that documentation, along with a plan of corrective action shall be submitted to the Department of Human Services within 10 working days of the laboratory's receipt of the survey results.
  - (d). Records shall be maintained indicating that proficiency samples are processed as routine specimens, shall identify the analyst performing the test, and indicate supervisory review and corrective action for unsatisfactory results. All records are subject to review by the department.
  - (e). At the discretion of the Department of Human Services, all laboratories are subject to on-site proficiency testing at any time tests are normally performed. Performance criteria shall be as specified in B above.
  - (f). If a laboratory does not perform satisfactorily as defined in B. above, it shall be subject to loss of its license to perform testing for drugs of abuse in general, or for the unsatisfactory analyte, pursuant to 5 MRSA, chapter 375, subchapter V, until two successive surveys have been satisfactorily tested.
  - (g). If a laboratory fails to comply with D(9), (c), (d), or (e), above, it may be required to file a documented plan of correction within 10 days, may be subject to conditional licensure, may lose its license to test for specific analytes, or may lose its license to perform testing for substances of abuse, pursuant to 5 MRSA, chapter 375, subchapter V.
10. The laboratory shall have a quality assurance program which encompasses all aspects of the testing process: specimen acquisition, chain of custody, security, and reporting of results,

in addition to the screening and confirmation analytical procedures.

- (a). Quality control procedures will be designed, implemented, and reviewed to monitor the conduct of each step of the process. These records shall be made available for review at the time of laboratory inspections.
  - (b). Control urine specimens containing no drugs, and specimens fortified with known standards, will be analyzed with each and every batch of specimens screened. Control specimens shall be comprise a minimum of 10 % of each day's processed specimens. Some controls with added drug or metabolite at or near the threshold (cutoff) level will be included. In addition, internal controls blind to the analyst shall be tested daily, and documented by the supervisor. Implementation of procedures to ensure that carry-over does not contaminate the testing of a subject's specimen must be documented.
  - (c). Quality control procedures must include validation of the performance of all automated sample processing and data processing equipment. Records shall be maintained concerning the repair and maintenance of all equipment.
- 11. Security measures must be maintained by the laboratory to ensure that access to areas where specimens are stored and processed, and where records are stored is strictly limited to authorized individuals only. Authorization shall be documented. Visitors, maintenance and service personnel must be escorted at all times, and their visits shall be documented.
  - 12. When specimens are received by the laboratory, receipts will be given, and the internal chain of custody will be established. The chain of custody shall document the time, date and purpose each time the specimen is handled or transferred, and identify the individuals involved.
  - 13. All positive specimens shall be retained in the original containers in secure storage at freezing temperatures (-20° C or less) for at least 6 months. Should legal challenge occur, the specimen will be retained throughout the period of resolution of the challenge.
  - 14. All laboratory reports, including the screening, confirmation and quality control data shall be reviewed by a certifying officer before being certified as accurate. The report shall identify the name of the laboratory, the drugs and metabolites tested for, whether the test results were negative or confirmed positive, and the cutoff levels for each substance. The report shall include any available information concerning the margin of accuracy and precision of the test methods employed.
    - (a). Unless agreed upon by the employee or applicant, no report shall show the quantity of substance detected, but only the presence or absence of that substance relative to the cutoff level.
    - (b). No report shall show that a substance was detected in a screening test, unless the presence of the substance was

confirmed in the confirmatory test. Procedures must be in place to ensure that an employee's unconfirmed positive screening test result cannot be determined by the employer in any manner, including, but not limited to, the method of billing the employer for the tests and the time within which results are provided to the employer.

- (c). No substance may be reported as present if the employer requesting the testing did not request analysis for that substance.
- (d). Reports of samples segregated at the employee's request, for testing by the employee's choice of laboratory, shall be provided to both the employee and the employer.

- 15. A laboratory aggrieved by any decision of the Department of Human Services regarding Approval shall have the rights of appeal specified in The Maine Administrative Procedure Act, Title 5, c. 375, and the Administrative Hearings Manual.

#### E. Confidentiality

- 1. Unless the employee or applicant consents, all test results and any information acquired by an employer in the testing process is confidential, and may not be released to any person other than the employee or applicant who was tested, any necessary personnel of the employer, and a provider of rehabilitation or treatment services. This requirement shall apply to personnel of all laboratories, as well as to employers. This paragraph does not prevent:
  - (a). The release of this information when required or permitted by state or federal law, including release under Title 26 MRSA, Section 683, subsection 8, paragraph D; or
  - (b). The use of this information in any grievance procedure, administrative hearing or civil action relating to the imposition of the test or the use of test results.
- 2. Notwithstanding any other law, the results of any substance abuse test required, requested or suggested by any employer may not be used in any criminal proceeding, as provided by 26 MRSA, section 685(3)(B).

#### F. Interdepartmental Communication.

The Department of Human Services shall inform the Department of Labor of any changes proposed or made in these rules to ensure necessary coordination between the rules of both Departments.

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STATUTORY AUTHORITY: 26 MRSA sections 681-690 and  
22 MRSA section 562  
PL 1990, chapter 832

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March 12, 2000 - restored missing language in C, D(8)